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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711,648	11/13/2000	Dean M. Ponzi	37646/KMO/W112	7874
23363	7590	09/20/2004	EXAMINER	
CHRISTIE, PARKER & HALE, LLP PO BOX 7068 PASADENA, CA 91109-7068			SIRMONS, KEVIN C	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/711,648

Applicant(s)

PONZI ET AL.

Examiner

Kevin C. Sirmons

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-11, 17-20, 22, 32, 33, 38 and 39 is/are allowed.
- 6) ☒ Claim(s) 1-8, 12-16, 21, 23-31, 34 and 35 is/are rejected.
- 7) ☒ Claim(s) 36, 37, 40 and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000))

Appropriate correction is required. See claim 36-41.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: See means for monitoring, claims 36-41.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-8, 23, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al U.S. Pat. No. 5,435,805.

Edwards discloses an injection catheter comprising: a catheter body comprising a flexible tubing having proximal and distal ends and at least one lumen therethrough (2); a tip section comprising a flexible tubing having proximal and distal ends, wherein the proximal end of the tip section is mounted at the distal end of the catheter body (figs. 15-23); a needle control handle at the proximal end of the catheter body (figs. 1 and 24); an injection needle extending through the tip section, catheter body, and needle control handle and having proximal end attached to the needle control handle and a distal end within the tip section, wherein the injection needle is longitudinally slidable within the tip section so that its distal end can extend out the distal end of the catheter upon suitable manipulation of the needle control handle (col. 6 and figs. 1 and 24); and an electrode lead wire having a first end electrically connected to the injection needle and a second end electrically connected to a suitable monitoring apparatus or to a source of ablation energy (figs. 1, 24 and the entire specification); as to claims 5-8, (see above listed figures and fig. 23); as to claims 23, 27 and 28 (see above rejection).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4 and 24-26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Edwards et al U.S. Pat. No. 5,435,805.

Edwards discloses an injection catheter substantially as claimed however, it may not be clear to someone who is not of ordinary skill in the art that the that the first end of the electrode lead wire is connected near the proximal end or distal end of the injection needle; or the number of wire or material. Therefore, it is the position of the examiner that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have a proximal and/or distal wire connection, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70. As to claims 4 and 26, (col. 42-63). Furthermore, the materials and number of wires are regarded as obvious to one having ordinary skill in the art (see fig. 1 for lead wires), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability fro the intended use a matter or obvious design choice. In re Leshin, 125 USPQ 416.

Claims 21 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards U.S. Pat. No. 5,435,805.

Edwards discloses an injection catheter substantially as claimed except for wherein the injection needle extends distally beyond the distal end of the tip section in a direction generally parallel to the axis of the catheter body. It would have been an obvious matter of design choice to change the shape to the tip section so that the injection needle can be parallel to the axis of the catheter body, since a modification would have involved a mere change in the shape of a

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component. A change in shape is generally recognized as being with the level of ordinary skill in the art. In re Daily, 357 F. 2d

Claims 12-16, 30, 31, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards U.S. Pat. No. 5,435,805 in view of Edwards U.S. Pat. No. 5,599,294 and further in view of Edwards 5,370,675.

Edward discloses an injection catheter substantially as claimed except for disclosing a method for introducing a therapeutic or diagnostic agent into heart tissue of a patient and the limitations of claims 13, 15 and 16.

Edwards discloses a method of using an injection catheter for introducing therapeutic or diagnostic agent into the heart tissue of a patient (Edwards '294' col. 5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Edwards device in the heart since Edwards (294) discloses that it would be readily apparent to a person skilled in the art that the device and method can be used to destroy body tissues in areas other than the prostate such as the brain, heart and/or other body cavities and tissue locations that are accessible by percutaneous or endoscopic catheters. Application of the device and method in all of these organs and tissues are intended to be included within the scope of this invention. As to claims 13 and 15, (Edwards '675'; col. 13, lines 5-18) and (col. 14, lines 1-11); as to claim 14, (Edwards '805' and see above rejection); as to claim 16, (Edwards '675' col. 3); as to claims 30, 31, 34, 35 (see above rejections).

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Response to Arguments

Applicant's arguments with respect to claims 1-41 have been considered but are moot in view of the new ground(s) of rejection.

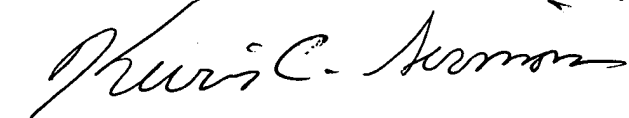
Allowable Subject Matter

Claims 9-11, 17-20, 22, 32, 33, 38 and 39 are allowable over the prior art of record.

Claims 36, 37, 40 and 41 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.



Kevin C. Sirmons
Patent Examiner
12/22/03